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HEADLINE: Vioxx whistle-blower speaks up on demoted antibiotic Ketek; Graham: 'Nothing has really changed' in FDA oversight

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BODY:

More than two years after David Graham told a Senate panel that the Food and Drug Administration was "incapable of protecting America against another Vioxx," the FDA scientist was back on Capitol Hill on Tuesday to tell a House panel that "nothing has really changed."

The nearly five-hour hearing before the House Subcommittee on Oversight and Investigations was only the first in what chairman Bart Stupak, D-Mich., says will be a series to "evaluate the Food and Drug Administration's ability to safely approve new drugs and provide post-marketing surveillance."

No FDA or drug company representatives were asked to speak at Tuesday's hearing, a decision that drew criticism from some committee members. "I'm disappointed that neither the FDA nor the manufacturer of Ketek ... were invited to tell their side," said Rep. Michael Burgess, R-Texas, who is a physician. "We must be cautious not to come to conclusions today."

Much of the testimony centered on the antibiotic Ketek, which has been linked to liver failure and other adverse side effects.

On Monday, the FDA announced that Ketek was no longer approved to treat sinusitis or bronchitis, because its potential risks outweigh any benefits for these fairly benign conditions. Ketek, approved in April 2004, remains on the market only to treat pneumonia acquired outside a hospital or nursing home.

"FDA approved Ketek, despite knowing that it could kill people from liver damage and that tens of millions of people would be exposed to it," physician David Ross, who had worked on the pre-approval side of FDA's Center for Drug Evaluation and Research (CDER) for a decade, told the panel. Ross said his superiors forced him to soften his unflattering review of the drug.

Lisa Kennedy, of Ketek maker Sanofi Aventis, told USA TODAY that Ketek can't be compared with Vioxx, the blockbuster arthritis drug pulled off the market in September 2004, because an FDA advisory panel in December supported the antibiotic's continued use for pneumonia.

Graham told panel members that CDER "regards industry as the agency's main client." Asked if he had concerns

about other drugs, Graham said off-label use of atypical antipsychotic medications to sedate nursing home residents kills roughly 15,000 people a year.

He also cited Zyprexa, used to treat schizophrenia and bipolar disorder, because, he said, maker Eli Lilly has known for years that the drug causes weight gain that leads to diabetes.

Lilly said in a statement that ever since Zyprexa was approved in 1996, its label has noted that weight gain and diabetes were observed in clinical trials.

Panel members asked Graham to submit the names of other potentially dangerous drugs. In an interview afterward, Graham declined to name the drugs before alerting the panel. He said he plans to submit his list next week after canvassing his colleagues to see if any drugs are "bugging" them.

GRAPHIC: PHOTO, B/W, Tim Dillon, USA TODAY

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